GOOD LABORATORY PRACTICES FOR WAIVED TESTING SITES REPORT

On November 11, 2005, the Centers for Disease Control and Prevention (CDC) published the report called "Good Laboratory Practices for Waived Testing Sites" in the Morbidity and Mortality Weekly Report. This report summarizes study findings and provides recommendations developed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for conducting quality waived testing. This report is available at: http://www.cdc.gov/mmwr/preview/mmwrhtm/rr5413a1.htm

FDA NOTICE ON IMPORTANT SAFETY INFORMATION IN INTERFERENCE WITH BLOOD GLUCOSE MEASUREMENT FOLLOWING USE OF PARENTERAL MALTOSE/PARENTERAL GALATOSE/ORAL XYLOSE-CONTAINING PRODUCTS

On November 9, 2005, the FDA sent a notice to alert physicians, nurses, medical technologists, pharmacists and other healthcare professionals of the potential for life-threatening falsely elevated glucose readings in patients who have received parenteral products containing maltose or galactose, or oral xylose, and are subsequently tested using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) based glucose monitoring systems. The GDH-PQQ method of glucose determination is non-specific for glucose and, in the presence of maltose, xylose, or galactose, may yield falsely elevated glucose readings. The FDA advised healthcare providers who prescribe a GDH-PQQ method of glucose determination to individuals for whom blood sugar measurements are routinely performed on an outpatient basis, to notify patients who may be receiving a parenteral product containing maltose or galactose, or oral xylose, to use only those glucose testing methodologies for blood sugar monitoring that are not subject to interference. This notice is available from the following FDA Internet site: http://www.fda.gov/cber/safety/maltose110405.htm

NEW WAIVED TESTS

On July 8, 2005, the Food and Drug Administration (FDA) approved the **Redi-Test Cassette Multi-Drug, Multi-Line Screen Test Device,** K050050/A002, for waived status for the analytes amphetamines, cocaine metabolites, cannabinoids, methamphetamines, opiates and phenycyclidine. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On July 8, 2005, the FDA approved the **iCasstette Multi-Drug, Multi-Line Screen Test Device,** K050050/A003, for waived status for the analytes amphetamines, cocaine metabolites, cannabinoids, methamphetamines, opiates and phenycyclidine. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On September 1, 2005, the FDA sent a letter to Akers Laboratories, Inc. that corrected the categorization letter of April 22, 2005. The name of the test system (K031579/A004)

was changed to **ReliaLab Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}** from Akers Laboratories Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}.

On September 27, 2005, the FDA approved the **Instant Technologies iScreen H. pylori Rapid Test Device**, K024350/A005, for waived status for the analyte Helicobacter pylori antibodies. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On September 27, 2005, the FDA approved the **Polymer Technology Systems CardioChek analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)** and the **Polymer Technology Systems CardioChek PA analyzer (PTS Panels CHOL+HDL Test Panel Test Strips)**, K023558/A001, for waived status for the analytes cholesterol, and HDL cholesterol. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On October 7, 2005, the FDA approved the **Instant Technologies iScreen Mononucleosis Rapid Test Strip {Whole Blood} and the Instant Technologies iScreen Mononucleosis Rapid Test Device {Whole Blood}**, K042272/A002, for waived status for the analyte infectious mononucleosis antibodies (mono). Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On October 20, 2005, the FDA approved the **Meridian Bioscience ImmunoCard STAT! RSV PLUS**, K041445/A004, for waived status for the analyte Respiratory Syncytial Virus. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On October 20, 2005, the FDA approved the **SA Scientific SAS RSV Test, Fisher Scientifice Sure-Vue RSV Test**, the **Remel Xpect RSV**, and the **SA Scientific SAS RSV Alert**, K022845/A007, for waived status for the analyte Respiratory Syncytial Virus. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On November 9, 2005, the FDA approved the **QuickVue iFOB Test (Immunochemical Fecal Occult Blood) {Cassette}**, K021423/A003, for waived status for the analyte fecal occult blood. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.

On December 1, 2005, the FDA approved the **BinaxNOW Influenza A & B Test {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}**, K041049/A003, for waived status for the analyte Influenza A/B. Waived status is applicable to the test system and its instructions as approved by the FDA. The FDA recommended that the test system instructions include a statement that the test is waived under CLIA.